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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,062	01/08/2002	Niels-Henrik Jensen	C12012/128608	4962
7590 06/17/2004 BRYAN CAVE LLP 1290 AVENUE OF THE AMERICAS, 33RD FLOOR NEW YORK, NY 10104			EXAMINER SINES, BRIAN J	
			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/043,062

Applicant(s)

JENSEN, NIELS-HENRIK

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 6, 8 – 14, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Seitz et al. (U.S. Pat. No. 5,015,843). Regarding claims 1 – 4, 13 and 14, Seitz et al. teach an optical sensor comprising: a hydrophilic water-swellaable polymeric matrix material comprising an analyte-sensitive indicator compound, such as a chelating ligand, bioreceptor or label, and a cyclic compound, such as a cyclodextrin, which has a three-dimensional structure forming a hydrophobic inner cavity and a hydrophilic exterior surface (see col. 13, lines 47 – 60; col. 15, lines 1 – 36). Regarding claim 5, Seitz et al. teach the incorporation of a membrane structure (see col. 5, lines 11 – 21). Regarding claim 6, Seitz et al. teach the use of polyvinyl alcohol (see col. 8, lines 57 – 68). Regarding claim 8, Seitz et al. teach that the sensor may be used to measure an analyte, such as urea, in a biological sample (see col. 15, lines 20 – 35). Regarding claim 9, Seitz et al. anticipate that the indicator compound may comprise a hydrophobic organic compound (see col. 8, lines 33 – 68). Regarding claims 10 – 12, Seitz et al. anticipate the incorporation of dyes (see col. 1, lines 23 – 38; col. 11, lines 54 – 67). Regarding claims 38 and 39, the use of the cyclodextrin polymer material, as disclosed by Seitz, appears to inherently anticipate the method of use recited in these claims (see col. 13, lines 47 – 61). Regarding product and apparatus claims, when the structure recited in the reference is

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substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnard et al. (U.S. Pat. No. 6,303,385 B2) in view of Seitz et al. (U.S. Pat. No. 5,015,843). Regarding claims 1 – 19, 21 and 22, Barnard et al. teach an optical sensing apparatus for pH determination, wherein the apparatus comprises a sensing membrane comprising a polymer matrix material (see col. 1, lines 1 – 65; col. 2, lines 30 – 54; col. 3, lines 19 – 67). Barnard et al. teach a membrane thickness of approximately 0.1 to 500  $\mu\text{m}$  (see col. 9, lines 29 – 33). Barnard et al. do not specifically teach the incorporation of a polymer matrix material, such as a cyclodextrin, which comprises an indicator compound having a three-dimensional structure forming a hydrophobic inner cavity and a

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hydrophilic exterior surface. Seitz et al. do teach the use of a cyclodextrin polymer material in optically-based chemical sensing applications. Seitz et al. teach an optical sensor comprising: a hydrophilic water-swelling polymeric matrix material comprising an analyte-sensitive indicator compound, such as a chelating ligand, bioreceptor or label, and a cyclic compound, such as a cyclodextrin, which has a three-dimensional structure forming a hydrophobic inner cavity and a hydrophilic exterior surface (see col. 13, lines 47 – 60; col. 15, lines 1 – 36). The Courts have held that the selection of a known material, based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success if incorporating the use of the cyclodextran polymer sensing material, as taught by Seitz, with the Barnard et al. apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art utilize a cyclodextrin polymer material as a sensing material in the apparatus of Barnard et al. in order to facilitate effective sensing operation. Regarding claims 20 and 37, Seitz et al. teach the use of polyvinyl alcohol (see col. 8, lines 57 – 68). Regarding claims 23 and 33, Seitz et al. anticipate that the indicator compound may comprise a hydrophobic organic compound (see col. 8, lines 33 – 68). Regarding claims 24 – 26 and 34 – 36, Seitz et al. anticipate the incorporation of dyes (see col. 1, lines 23 – 38; col. 11, lines 54 – 67). Regarding claims 27 – 32, Seitz et al. anticipate a method of incorporating an indicator

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compound, such as a covalently-bound bioreceptor, with the cyclodextrin polymer matrix (see col. 15, lines 20 – 27).

### *Conclusion*

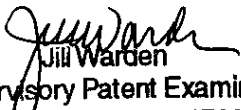
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Offenbacher et al. teach a polymer membrane cover layer for an optical ion sensor. Wolfbeis et al. teach the use of a polymer membrane sensor layer in an optical detection apparatus. Alder et al. teach an optical detection system for determining pH. Luo et al. teach an optical chemical detection system incorporating the use of dyes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700